Attorney Docket No. UNIE-014/01US

PATENT

1647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Alan SOLOMON et al. Group Art Unit: 1647

Serial No.: 09/316,387 Examiner: S. Turner

Filed: May 21, 1999

For: METHODS FOR AMYLOID REMOVAL USING ANTI-AMYLOID ANTIBODIES

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TRANSMITTAL OF RESPONSE

Enclosed are the following documents in supplement to the documents filed December 20, 2005 in connection with the above-identified application:

[X] Executed Declaration Under 37 CFR § 1.131
[] Other:

The fee has been calculated as follows:

	NO. OF CLAIMS	CLAIMS PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	48	- 48 =	0	x $50.00	$0.00
Independent Claims	5	- 5 =	0	x $200.00	$0.00
If multiple dependent claims are presented, add $360.00					
Total Amendment Fee					$0.00
If small entity status is applicable, subtract 50% of Total Amendment Fee					
Other fees:					$0.00
TOTAL FEE DUE					$0.00

[] A check for the total fee is attached.

[] Please charge $0.00 to Deposit Account No. 50-1283 for the total fee. This paper is being submitted in duplicate.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Respectfully submitted,
COOLEY GODWARD LLP

Dated: 3-6-06

By: _____
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PATENT
Attorney Docket **044137-5025-01**

PRIVILEGED AND CONFIDENTIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Alan Solomon *et al.***	)	
Application No. **09/316,387**	)	Group Art Unit: **1647**
Filed: **May 21, 1999**	)	Examiner: **Sharon Turner**
For: **Methods for Amyloid Removal Using Anti-amyloid Antibodies**	)	

DECLARATION UNDER 37 C.F.R. § 1.131

We Alan Solomon, Rudi Hrncic and Jonathan Stuart Wall, declare as follows:

1. We are the named inventors of the above referenced application (Ser. No. 09/316,387).

2. We have read and understand the Office Action of June 20, 2005, in particular the rejection of the pending claims under 35 U.S.C. § 102(e) over U.S. Patent 6,743,427 (the '427 patent) and U.S. Patent 6,787,523 (the '523 patent).

3. We understand that the earliest asserted priority date of the '427 and '523 patents is December 2, 1997 through the priority claim to U.S. Provisional Application Ser. No. 60/067,740.

4. We invented the subject matter of the pending claims before December 2, 1997. In one embodiment, monoclonal antibodies anti-κ1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti-κ8 (31-8c7), deposited as ATCC Acc. No. PTA-103 are disclosed in our U.S. Application Ser. No. 09/316,387.

5. Exhibit A, dated before December 2, 1997, shows that antibodies anti-κ1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti-κ8 (31-8c7), deposited as ATCC Acc. No. PTA-103 bind to different types of amyloid fibrils, including amyloid

fibrils consisting of Aβ peptide by ELISA analysis (see rows G & H wherein Aβ 25-35 was incubated with antibody 57-18H12 (Columns 1 & 2) or antibody 31.8c7 (columns 9 & 10)).

6. Exhibit B, dated before December 2, 1997, shows that antibodies anti-κ1 (57-18H12), deposited as ATCC Acc. No. PTA-104 and anti-κ8 (31-8c7), deposited as ATCC Acc. No. PTA-103 remove amyloidoma masses when administered in an effective amount in a mouse model (see photographs of mice wherein the mice, previously injected with amyloid material, exhibit complete removal of the amyloidoma after administration of the antibody).

7. We each further declare that all statements made herein on our own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Respectfully submitted,

Alan Solomon — Date: 1/12/06

Rudi Hrncic — Date: 02/09/06

Jonathon Stuart Wall — Date: 2/9/06

USING SAME Abs AS [redacted] — PREVIOUS RESULTS
GIVEN HERE 15-18 ml [redacted]

Block : 57-18H12, λVI, Free κ, Free λ, λVIII, :
11-1F4,

Column labels: κI 57-18H12 (1–2); κIV 11-1F4 (3–4); 4lk-C8 (5–6); λVI 55-5F3 (7–8); VIII 36-8C7 (9–10); 18-9G11 Free λ (11–12)

2 µg protein (total) in Ea. well.

Row labels: Jmas λVI (A–B); Hig κI (C–D); 910 λVI (E–F); 25-35 Aβ (G–H)

	1	2	3	4	5	6	7	8	9	10	11	12
A		2		2			2	3	5	6	2	2
B	2	2		2			3	3	6	6	2	2
C	2	3		2			2	2	6	6	2	2
D	2	3		2			2	2	5	6	2	2
E	2	2		2			2	2	4	4	2	2
F	2	2		2			2	2	4	4	2	2
G	2	2		2			2	2	5	5	2	2
H	2	2		2			2	2	5	5	2	2

Scores ≥2 shown only

Block 1°
Add Mollis
Add [redacted]

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

BIO TEK MICROPLATE READER [redacted] 00008208

ASSAY# _____

PLATE# _____ OPERATOR _____

NOTES _____

PROGRAM MODE #5 SINGLE WAVELENGTH: 405

TABLE OF ABSORBANCE VALUES

	2	3	4	5	6	7	8	9	10	11	12
A	0.366	0.512	0.312	0.446	0.246	0.333	0.555	0.615	1.148	1.207	0.463	0.473
B	0.424	0.484	0.353	0.445	0.290	0.330	0.690	0.668	1.177	1.248	0.493	0.524
C	0.558	0.621	0.378	0.454	0.354	0.387	0.440	0.487	1.281	1.268	0.476	0.470
D	0.546	0.633	0.356	0.485	0.334	0.399	0.424	0.492	1.161	1.333	0.420	0.481
E	0.419	0.486	0.340	0.434	0.271	0.287	0.485	0.485	0.943	0.993	0.419	0.409
F	0.423	0.493	0.355	0.446	0.281	0.312	0.565	0.578	0.959	0.992	0.458	0.440
G	0.441	0.541	0.379	0.525	0.312	0.369	0.476	0.535	1.053	1.191	0.472	0.496
H	0.457	0.549	0.393	0.505	0.310	0.364	0.499	0.500	1.119	1.178	0.474	0.499

TABLE OF RANGES

BIN # :	0	1	2	3	4	5	6	7	8	9
RANGES:	0.000	0.200	0.400	0.600	0.800	1.000	1.200	1.400	1.600	1.800	2.000

	1	2	3	4	5	6	7	8	9	10	11	12
A	1	2	1	2	1	1	2	3	5	6	2	2
B	2	2	1	2	1	1	3	3	6	6	2	2
C	2	3	1	2	1	1	2	2	6	6	2	2
D	2	3	1	2	1	1	2	2	5	6	2	2
E	2	2	1	2	1	1	2	2	4	4	2	2
F	2	2	1	2	1	1	2	2	4	4	2	2
G	2	2	1	2	1	1	2	2	5	5	2	2
H	2	2	1	2	1	1	2	2	5	5	2	2